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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/065,280	09/30/2002	Jeffrey C. Leung	2284.40532	5694
83532	7590	07/28/2010		
ANGIOTECH P. O. BOX 2840 NORTH BEND, WA 98045			EXAMINER DOWE, KATHERINE MARIE	
			ART UNIT 3734	PAPER NUMBER
			NOTIFICATION DATE 07/28/2010	DELIVERY MODE ELECTRONIC

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Notice of the Office communication was sent electronically on above-indicated "Notification Date" to the following e-mail address(es):

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Office Action Summary

Application No.

10/065,280

Applicant(s)

LEUNG ET AL.

Examiner

KATHERINE M. DOWE

Art Unit

3734

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 19 May 2010.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-3, 6-9, 12-20, 22, 31-38, 51-62, 69, 70 and 77-82 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-3, 6-9, 12-20, 22, 31-38, 51-62, 69, 70 and 77-82 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- 1) ☐ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-944)
- 3) ☐ Information Disclosure Statement(s) (PTO/SB/08)
Paper No(s)/Mail Date _____
- 4) ☐ Interview Summary (PTO-413)
Paper No(s)/Mail Date _____
- 5) ☐ Notice of Informal Patent Application
- 6) ☐ Other: _____

DETAILED ACTION

1. The following is in response to the amendment filed May 19, 2010.
2. Claims 1-3, 6-9, 12-20, 22, 31-38, 51-62, 69, 70, and 77-82 are currently pending.

Terminal Disclaimer

3. The terminal disclaimer filed on May 19, 2010 disclaiming the terminal portion of any patent granted on this application which would extend beyond the expiration date of any patent granted on Application Number 10/065,279 has been reviewed and is accepted. The terminal disclaimer has been recorded.

Claim Rejections - 35 USC § 103

4. The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.
5. Claims 1-3, 6-9, 12-20, 22, 31-38, 51-62, 69, 70, and 77-82 are rejected under 35 U.S.C. 103(a) as being unpatentable over Buncke (US 5,931,855) in view of Morency et al. (US 2003/0149447, hereinafter "Morency"). Regarding claims 1-3, 12-15, 31-38, Buncke discloses the invention substantially as claimed including a barbed suture (Figures 9-11) comprising an elongate body having a first end and a second end and a plurality of barbs (16) projecting from the body. The barbs are arranged in a multiple spiral disposition wherein the barbs are spaced longitudinally along the body such that a plane perpendicular to the longitudinal axis of the suture and cutting transversely through the suture and intersecting a barb will not intersect any other barb (Figures 9-11; col 4, ln 58-59; col 9, ln 5-8). In a first barb portion (55a) all of the barbs are only facing toward a first end of the elongate body and in a second barb portion (55b) all of the barbs are only facing toward a second end of the elongate body (col 6, ln 60-67). The

suture may be made of a non-absorbable material including polyester or made of a bio-absorbable material including polylactide or polyglycolide (col 1, ln 20-23).

However, Buncke does not disclose an arcuate base at the underside of the barbs. Morency discloses a similar barbed suture (Fig 1A) with a plurality of barbs (24) along an elongated suture body (22). Morency teaches the barbs may be rounded on both the topside of the barb (74) and underside of the barb (76) when the suture is used in delicate tissue prone to tearing (¶0040; Fig 1G). Therefore, it would have been obvious to one having ordinary skill in the art at the time the invention was made to modify the device of Buncke such that the base at the underside of the barbs was arcuate to prevent tearing of delicate tissue.

Regarding claims 6-9, 16-20, 22, 51-62, 69, 70, and 77-82, Buncke does not disclose does not disclose the specific dimensions of the spirality angle, the barb cut angle, the ratio of the barb cut depth to the suture diameter, the ratio of the barb cut length to the suture diameter, or the ratio of the barb cut distance to the suture diameter. Applicant has not disclosed that having a spirality angle of 12-18 degrees, a barb cut angle of 140-175 degrees, a ratio of barb cut depth to suture diameter of 0.05-0.6, a ratio of barb cut length to suture diameter of 0.2-2, or a ratio of barb cut distance to suture diameter of 0.1-6 solves any stated problem or is for any particular purpose. Moreover it appears that the barbed suture of the combination of Buncke and Morency, or applicant's invention, would perform equally well with the suture having any appropriate dimension. Accordingly, it would have been prima facie obvious to one of ordinary skill in the art at the time the invention was made to have modified the combination of Buncke and Morency such that the suture had a spirality angle of 12-18 degrees, a barb cut angle of 140-175 degrees, a ratio of barb cut depth to suture diameter of 0.05-0.6, a ratio of barb cut length to suture diameter of 0.2-2, and a ratio of barb cut distance to suture diameter of 0.1-6 because such a modification would have been considered a mere design consideration which

fails to patentably distinguish over the combination of Buncke and Morency. Furthermore, it would have been obvious to one having ordinary skill in the art at the time the invention was made to modify the combination of Buncke and Morency to incorporate the above parameters since it has been held that where the general conditions of a claim are disclosed in the prior art, discovering the optimum or workable ranges or the an optimum value involves only routine skill in the art (see *In re Aller*, 105 USPQ 233, *In re Boesch*, 617 F.2d 272, 205 USPQ 215, and MPEP 2144.05).

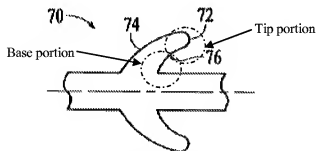
Additionally, Buncke does not disclose the suture is twisted 2 to 17 times per inch to form the multiple spiral disposition. However, the claim language regarding twisting the suture 2 to 17 times per inch is being treated as a product by process limitation. As set forth in MPEP 2113, product by process claims are NOT limited to the manipulations of the recited steps, only to the structure implied by the steps. Once a product appearing to be substantially the same or similar is found, a 35 U.S.C. 102/103 rejection may be made and the burden shifted to the applicant to show an unobvious *structural* difference in the product. The Examiner contends the combination of Buncke and Morency discloses a suture having barbs in a multiple spiral disposition (Figures 9-11).

Response to Arguments

6. Applicant's arguments filed May 19, 2010 have been fully considered but they are not persuasive.
7. Applicant acknowledges Morency teaches an arcuate portion on the underside of the barb. However, Applicant argues the arcuate portion cannot be interpreted as the claimed "base". In response to applicant's argument that the references fail to show certain features of applicant's invention, it is noted that the features upon which applicant relies (i.e., the term

"base" denoting the precise junction between the suture body and the suture barb; in other words, the "base" of the barb referring to the "line" where the barb joins to the suture body - see Applicant's remarks on the second paragraph of page 2) are not recited in the rejected claim(s). Although the claims are interpreted in light of the specification, limitations from the specification are not read into the claims. See *In re Van Geuns*, 988 F.2d 1181, 26 USPQ2d 1057 (Fed. Cir. 1993).

8. The examiner notes the claims merely recite, "...the suture comprising barbs with a configuration that includes an arcuate base at the underside of the barbs...". Applicant does not provide a special definition of the base, and thus the base may be interpreted as the portion of the underside of the barb adjacent the suture body, as opposed to the tip portion of the barb, wherein the base portion is arcuate. See annotated Figure 1G below:



Conclusion

9. **THIS ACTION IS MADE FINAL.** Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

10. Any inquiry concerning this communication or earlier communications from the examiner should be directed to KATHERINE M. DOWE whose telephone number is (571)272-3201. The examiner can normally be reached on M-F 8:30am - 5pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Todd Manahan can be reached on (571) 272-4713. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Art Unit: 3734

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

Katherine Dowe
July 21, 2010

/K. M. D./
Examiner, Art Unit 3734

/TODD E. MANAHAN/

Supervisory Patent Examiner, Art Unit 3734